**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| SIGHT SCIENCES, INC.<br><br>Plaintiff,<br><br>v.<br><br>IVANTIS, INC.,<br><br>Defendant. | C.A. No. 21-cv-1317-LPS<br><br>**JURY TRIAL DEMANDED** |

**DEFENDANT IVANTIS, INC.'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT AND COUNTERCLAIMS**

Ivantis is a company dedicated to the development of innovative solutions for glaucoma therapy. Ivantis' Hydrus® Microstent is a groundbreaking, minimally invasive glaucoma surgery (MIGS) technology implant indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG). Sight Sciences is not now, and never has been, in the business of selling surgical implants for the treatment of glaucoma. Sight Sciences does not sell any products that practice U.S. Patent Nos. 8,287,482; 9,370,443; 9,486,361; and 10,314,742 (collectively, the "Patents-in-Suit"). Ivantis does not infringe the Patents-in-Suit, which are invalid.

**ANSWER**

Defendant Ivantis, Inc. ("Ivantis" or "Defendant") demands a trial by jury on all issues so triable and answers Plaintiff Sight Sciences, Inc.'s ("Sight Sciences" or "Plaintiff") First Amended Complaint and states its affirmative defenses and counterclaims against Sight Sciences as follows:

## THE PARTIES[1]

1. Upon information and belief, admitted.

2. Ivantis admits that it is a Delaware corporation, with its corporate headquarters at 201 Technology Dr., Irvine, CA 92618.

## JURISDICTION AND VENUE

3. Ivantis admits that the First Amended Complaint purports to set forth claims for patent infringement, but denies Ivantis has committed or is committing acts of patent infringement. Ivantis admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

4. Ivantis admits that it is incorporated in Delaware. Ivantis admits that, pursuant to 28 U.S.C. § 1400(b), venue is proper in this district for purposes of this action. Ivantis denies any and all remaining allegations of paragraph 4.

5. Ivantis admits that it is incorporated in Delaware. Ivantis admits that this Court has personal jurisdiction over it for purposes of this action. Ivantis denies any and all remaining allegations of paragraph 5.

## FACTUAL ALLEGATIONS

### I. SIGHT SCIENCES IS A LEADER IN INNOVATING NEW GLAUCOMA TREATMENT DEVICES AND METHODS

6. Ivantis admits that glaucoma is a potentially blinding disease that affects over 60 million people worldwide, and is a condition of the eye that is typically caused by excessive intraocular pressure, or IOP. Ivantis admits that human eyes contain a clear, colorless, and continuously replenished fluid known as "aqueous humor," which is generated by the "ciliary

[1] For ease of reference, Ivantis adopts the headings set forth in the First Amended Complaint. To the extent that such headings themselves contain factual or legal characterizations or allegations, Ivantis denies such characterizations and allegations.

body," a structure in the posterior chamber of the eye that lies beneath the iris. Ivantis admits that in a healthy eye the aqueous humor generated by the ciliary body flows unobstructed through the pupil into the anterior chamber, and that aqueous humor exits from the anterior chamber through the eye's natural drainage system, known as the trabeculocanalicular outflow pathway. Ivantis admits that the eye's natural drainage system comprises a trabecular meshwork, Schlemm's canal, and about 30-40 collector or drainage channels around the eye that connect to the venous system so that aqueous humor can flow into the bloodstream and leave the eye. Ivantis denies any and all remaining allegations of paragraph 6.

7. Ivantis admits that in primary open-angle glaucoma ("POAG") patients, the outflow or drainage system of the eye, including the trabecular meshwork, Schlemm's canal, and about 30-40 collector or drainage channels, can become obstructed. Ivantis admits that if aqueous humor accumulates and the fluid pressure inside the eye increases, this can cause damage to the optic nerve and lead to irreversible blindness if left untreated. Ivantis admits that treatments to reduce intraocular pressure in the eye are desirable for patients suffering from POAG. Ivantis lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 7, and therefore denies those allegations.

8. Ivantis admits that elevated IOP can be treated using multiple modalities, including medication, incisional surgery, laser surgery, or other forms of surgery, and that medication may not be sufficient for some patients. Ivantis lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 8, and therefore denies those allegations.

9. Ivantis admits that implants known as trabecular micro-bypass stents were inserted between the anterior chamber of the eye and Schlemm's canal, bypassing a small section of the

diseased trabecular meshwork. Ivantis lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 9, and therefore denies those allegations.

10. Ivantis lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 10, and therefore denies those allegations.

11. Ivantis admits that the face of U.S. Patent No. 7,909,789 (the "'789 patent") lists U.S. Appl. No. 11/475,525 (the "'523 application") and identifies David Y. Badawi and Paul Badawi as inventors. Ivantis lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 11, and therefore denies those allegations.

12. Ivantis admits that the specification filed with the '523 application states that it describes "devices, kits and methods [that] relate to intraocular implants implantable into Schlemm's canal that can reduce intraocular pressure without substantially interfering with fluid flow across Schlemm's canal." Ivantis lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 12, and therefore denies those allegations.

13. Ivantis lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 13, and therefore denies those allegations.

14. Ivantis lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 14, and therefore denies those allegations.

## II. THE PATENTS-IN-SUIT

15. Ivantis admits that the face of the '443 patent purports to be a division of application No. 11/475,523, now Pat. No. 7,909,789. Ivantis further admits that the face of the '742 patent purports to be a continuation of application No. 13/025,112, "now Pat. No. 9,370,443, which is a division of application No. 11/475,523," now Pat. No. 7,909,789. Ivantis further admits that the face of the '482 patent purports to be a continuation of application No. 11/475,523, now Pat. No. 7,909,789. Ivantis further admits that the face of the '361 patent purports to be a continuation of

application No. 12/695,053, now Pat. No. 8,287,482, which is purportedly a continuation of 11/475,523, now Pat. No. 7,909,789. Ivantis denies any and all remaining allegations of paragraph 15.

16. Ivantis admits that the face of the '482 patent states that it was filed January 27, 2010 and that the issue date on the face of the '482 patent is October 16, 2012. Ivantis further admits that Plaintiff's First Amended Complaint purports to attach a copy of the '482 patent as Exhibit A, the face of which includes the title "Intraocular Implants and Methods and Kits Therefore." The remaining allegations of paragraph 16 either contain conclusions of law for which no response is required, or Ivantis lacks knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. To the extent an answer is required, Ivantis denies any and all remaining allegations of paragraph 16.

17. Ivantis admits that the face of the '443 patent states that it was filed February 10, 2011 and that the issue date on the face of the '443 patent is June 21, 2016. Ivantis further admits that Plaintiff's First Amended Complaint purports to attach a copy of the '443 patent as Exhibit B, the face of which includes the title "Intraocular Implants and Methods and Kits Therefore." The remaining allegations of paragraph 17 either contain conclusions of law for which no response is required, or Ivantis lacks knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. To the extent an answer is required, Ivantis denies any and all remaining allegations of paragraph 17.

18. Ivantis admits that the face of the '361 patent states that it was filed April 12, 2012 and that the issue date on the face of the '361 patent is November 8, 2016. Ivantis further admits that Plaintiff's First Amended Complaint purports to attach a copy of the '361 patent as Exhibit C, the face of which includes the title "Intraocular Implants and Methods and Kits Therefore." The

remaining allegations of paragraph 18 either contain conclusions of law for which no response is required, or Ivantis lacks knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. To the extent an answer is required, Ivantis denies any and all remaining allegations of paragraph 18.

19. Ivantis admits that the face of the '742 patent states that it was filed June 14, 2016 and that the issue date on the face of the '742 patent is June 11, 2019. Ivantis further admits that Plaintiff's First Amended Complaint purports to attach a copy of the '742 patent as Exhibit D, the face of which includes the title "Intraocular Implants and Methods and Kits Therefore." The remaining allegations of paragraph 19 either contain conclusions of law for which no response is required, or Ivantis lacks knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. To the extent an answer is required, Ivantis denies any and all remaining allegations of paragraph 19.

## III. IVANTIS ATTEMPTED TO PURCHASE, HAS REMAINED AWARE OF, AND WILLFULLY INFRINGES, SIGHT SCIENCE'S PATENTED TECHNOLOGY

20. Ivantis admits it is a privately held company that was founded in 2007 to, among other things, design, develop, and commercialize new technologies to treat eye disease. Ivantis lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 20, and therefore denies those allegations.

21. Ivantis admits that the face of U.S. Pub. No. 2007/0298068 lists Appl. No. 11/475,523, and that December 27, 2007 is listed on the face of U.S. Pub. No. 2007/0298068 as the publication date.

22. Ivantis admits that in or around December 2008 an email was sent to the Badawi brothers or their representatives related to U.S. Publ. No. 2007/0298068. Ivantis lacks sufficient

knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 22, and therefore denies those allegations.

23. Ivantis admits that the issue date on the face of the '789 patent is March 22, 2011. Ivantis admits that in or around December 2008 Doug Roeder met with one or more of the Badawi brothers and discussed, among other things, U.S. Publ. No. 2007/0298068. Ivantis lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 23, and therefore denies those allegations.

24. Ivantis denies that it competes with Sight Sciences in the market for minimally invasive surgical glaucoma therapies. Ivantis admits that it gathers certain market data related to Sight Sciences. Ivantis denies any and all remaining allegations of paragraph 24.

25. Ivantis admits that Shay Glenn LLP has represented Ivantis since around 2008. Ivantis denies any and all remaining allegations of paragraph 25.

26. Ivantis admits that its website lists U.S. Patent Nos. 7,740,604; 8,337,509; 8,372,026; 8,425,449; 8,512,404; 8,663,150; 8,734,377; 8,961,447; 9,039,650; 9,050,169; 9,211,213; 9,226,852; 9,351,874; 9,402,767; 9,610,196; and 9,693,899 for the Hydrus® Microstent to serve as notice under 35 U.S.C. § 287(a). Ivantis admits that U.S. Patent No. 9,358,156 and U.S. Patent No. 11,026,836 are assigned to Ivantis, Inc. Ivantis admits that the '156 patent lists U.S. 2007/0298068; U.S. 2011/0196487; U.S. 2013/0253402; U.S. 2013/0253403; U.S. 2013/0253437; and U.S. 2013/0253438 to Badawi et al. on its face under "References Cited." Ivantis admits that the '836 patent lists U.S. 2007/0298068; U.S. 2011/0196487; U.S. 2013/0253402; U.S. 2013/0253403; U.S. 2013/0253437; U.S. 2013/0253438; and U.S. 2017/0143541 to Badawi et al. on its face under "References Cited." Ivantis denies any and all remaining allegations of paragraph 26.

27. Ivantis admits that Plaintiff's First Amended Complaint purports to attach a copy of PCT Application PCT/US2016/066957 as Exhibit I. Ivantis denies any and all remaining allegations of paragraph 27.

28. Ivantis admits that David T. Van Meter and Kenneth M. Galt are listed as inventors on PCT Application PCT/US2016/066957, and that an International Search Report for PCT/US16/66957 lists U.S. Patent No. 8,287,482 as a "document defining the general state of the art which is not considered to be of particular relevance." Ivantis denies any and all remaining allegations of paragraph 28.

29. Denied.

30. Denied.

## IV. IVANTIS DEVELOPED, MARKETED, AND SOLD ITS INFRINGING HYDRUS® PRODUCT KNOWING IT INFRINGED SIGHT SCIENCES' PATENTS

31. Ivantis admits that it commenced a study titled "The Safety and Effectiveness of the Hydrus Aqueous Implant for Lowering Intraocular Pressure in Glaucoma Patients Undergoing Cataract Surgery, A Prospective, Multicenter, Randomized, Controlled Clinical Trial" in January 2012, also referred to as the HORIZON study. Ivantis further admits that the primary completion date of the study was in June 2017. Ivantis denies any and all remaining allegations of paragraph 31.

32. Ivantis admits that on or about August 10, 2018, the FDA issued an Approval Order for its premarket approval application ("PMA") for the Hydrus® Microstent, which is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG). Ivantis admits that it thereafter began selling the Hydrus® Microstent. Ivantis denies any and all remaining allegations of paragraph 32.

33. Ivantis admits that the '482 patent (at 2:56-59), the '443 patent (at 2:58-61), the '361 patent (at 2:61-64), and the '742 patent (at 2:61-64) state that "[t]he devices for reducing pressure within the eye comprise a support implantable circumferentially within Schlemm's canal that is configured to maintain the patency of at least a portion of the canal." Ivantis denies any and all remaining allegations of paragraph 33.

34. Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that "[t]he implant is laser cut from nitinol tubing to a proprietary design with alternating 'spines' for structural support and 'windows' to provide outflow pathways for aqueous humor." Ivantis further admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that "[t]he implant is designed to have adequate structural thickness to support the tissue of the canal while providing maximum open flow areas through the canal, with the proximal portion of the implant exiting the canal through the trabecular meshwork to allow inflow of aqueous humor from the anterior chamber." Ivantis further admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that "nitinol has super-elastic properties making it suitable as a support structure in Schlemm's canal." Ivantis denies any and all remaining allegations of paragraph 34.

35. Ivantis admits that the figure in paragraph 35 appears in the Hydrus® Microstent Instructions for Use (C00256 Rev A.1). Ivantis denies any and all remaining allegations of paragraph 35.

36. Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that the "microstent is implanted into the eye using a hand-held delivery system . . . that provides for delivery of the implant through a stainless steel cannula into the target site in the eye. The delivery system was designed to provide smooth tracking and controlled delivery of the microstent into Schlemm's canal." Ivantis admits that the Hydrus® Microstent Instructions for

Use (C00256 Rev A.1) state that "[t]o accommodate a wide range of hand positions, a rotatable sleeve at the distal end allows positioning and alignment of the cannula by the surgeon to direct the implant into Schlemm's canal. The tracking wheel on the delivery system serves as the control mechanism to advance the implant into the canal or retract the implant into the cannula." Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state "The Hydrus® Microstent is a crescent-shaped implantable microstent pre-loaded onto a hand held delivery system." Ivantis denies any and all remaining allegations of paragraph 36.

37. Ivantis admits that the image in paragraph 37 purports to be from a video describing the Hydrus® Microstent. Ivantis further admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that the "microstent is implanted into the eye using a hand-held delivery system . . . that provides for delivery of the implant through a stainless steel cannula into the target site in the eye. The delivery system was designed to provide smooth tracking and controlled delivery of the microstent into Schlemm's canal." Ivantis denies any and all remaining allegations of paragraph 37.

38. Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that the "length and curvature of the implant are designed to occupy approximately 90° or 3 clock hours of Schlemm's canal." Ivantis further admits that the figures in paragraph 38 appear in the Hydrus® Microstent Instructions for Use (C00256 Rev A.1). Ivantis denies any and all remaining allegations of paragraph 38.

39. Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that part of the microstent procedure includes "[v]erify[ing] that the inlet of the microstent is positioned in the anterior chamber." Ivantis further admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that the "the proximal portion of the implant exiting

the canal through the trabecular meshwork [is] to allow inflow of aqueous humor from the anterior chamber." Ivantis further admits that Figure 5 of the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that it "shows the microstent positioned in Schlemm's canal with the proximal end (i.e., the inlet) protruding slightly into the anterior chamber for inflow of aqueous humor." Ivantis further admits that the images in paragraph 39 purport to be from a video describing the Hydrus® Microstent. Ivantis denies any and all remaining allegations of paragraph 39.

40. Ivantis admits that the voiceover of the Hydrus® Animation that purports to be from a video describing the Hydrus® Microstent makes the statement provided in the block quote ("The Hydrus® Microstent acts. . . aqueous outflow veins") of paragraph 40. Ivantis denies any and all remaining allegations of paragraph 40.

41. Ivantis admits that the image in paragraph 41 purports to be from a video describing the Hydrus® Microstent. Ivantis denies any and all remaining allegations of paragraph 41.

42. Ivantis admits that the screenshots in paragraph 42 purport to be from an animation describing the Hydrus® Microstent. Ivantis denies any and all remaining allegations of paragraph 42.

43. Denied.

44. Ivantis admits that the '482 patent at 11:16-20; the '443 patent at 11:16-20; the '361 patent at 11:29-33; and the '742 patent at 11:30-34 state "[t]he fraction of canal wall surface area in contact with a support can be estimated by viewing the inside of Schlemm's canal as a slightly arcuate cylinder C having length L, extending circumferentially from a first end X1 to a second end X2 of support 152, and inside radius Ri." Ivantis denies any and all remaining allegations of paragraph 44.

45. Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that the "microstent is approximately 8mm in overall length with major and minor axes of 292µm and 185µm, respectively." Ivantis further admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that "the proximal portion of the implant exit[s] the canal through the trabecular meshwork to allow inflow of aqueous humor from the anterior chamber." Ivantis denies any and all remaining allegations of paragraph 45.

46. Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that "[t]he implant is laser cut from nitinol tubing to a proprietary design with alternating 'spines' for structural support and 'windows' to provide outflow pathways for aqueous humor." Ivantis further admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that the "microstent is approximately 8mm in overall length with major and minor axes of 292µm and 185µm, respectively," and that "[t]he implant is designed to have adequate structural thickness to support the tissue of the canal while providing maximum open flow areas through the canal, with the proximal portion of the implant exiting the canal through the trabecular meshwork to allow inflow of aqueous humor from the anterior chamber." Ivantis denies any and all remaining allegations of paragraph 46.

47. Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that the "microstent is approximately 8mm in overall length with major and minor axes of 292µm and 185µm, respectively." Ivantis denies any and all remaining allegations of paragraph 47.

48. Denied.

49. Denied.

50. Denied.

51. Ivantis admits that Murray A. Johnstone et al., *Effects of a Schlemm canal scaffold on collector channel ostia in human anterior segments,* 119 Experimental Eye Research 70 (2014) (the "Johnstone article"), lists Andrew T. Schieber as a co-author and states "Supported by Ivantis Inc., and an unrestricted grant from Research to Prevent Blindness." Ivantis admits that the Johnstone article contains a Figure 6 that has a caption stating "Pictorial overlay (black solid lines) of 8 mm (A) and 15 mm (B) microstents on the Fig. 5. Scanning electron microscopy image comparing the effects microstent placement on the outer wall of Schlemm's canal (SC). The overlay shows how the microstent bridged an area of the external wall of SC." Ivantis lacks knowledge or information sufficient to form a belief about the truth of Plaintiff's remaining allegations and therefore denies them.

52. Ivantis admits that the Johnstone article contains a Figure 5 that has a caption that refers to the Schlemm's canal external wall as SCEW. Ivantis admits that the caption also states that the "[d]otted areas outline microstent generated indentations." Ivantis lacks knowledge or information sufficient to form a belief about the truth of Plaintiff's remaining allegations and therefore denies them.

53. Ivantis admits that Saba Samet et al., *Hydrus microstent implantation for surgical management of glaucoma: a review of design, efficacy and safety*, Eye and Vision, 6:32 (2019), available at https://eandv.biomedcentral.com/track/pdf/10.1186/s40662-019-0157-y.pdf (hereinafter the "Samet article"), contains a Figure 3 that has a caption stating "Scanning electron microscopic image of SC outer wall following insertion and removal of an 8 mm Hydrus microstent, with collector channel ostia shown in panels a-d. Particulate debris visible in image (a) (barred arrows). The intact but sloping edge of the collector channel ostium (shown in d) resulting from microstent-dependent indentation appearing to compress the lower portion of the

ostia while leaving the upper portion open. Courtesy of Johnstone et al." Ivantis lacks knowledge or information sufficient to form a belief about the truth of Plaintiff's remaining allegations and therefore denies them.

54. Ivantis lacks knowledge or information sufficient to form a belief about the truth of Plaintiff's allegations and therefore denies them.

55. Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that the "implant is laser cut from nitinol tubing to a proprietary design with alternating 'spines' for structural support and 'windows' to provide outflow pathways for aqueous humor." Ivantis admits that the Samet article contains a Figure 2 that has a caption stating "Hydrus and iStent devices in situ. (a) Histological section of the Hydrus scaffold window region in situ showing SC dilatation. Histological section of the iStent micro-bypass rail in situ. Images courtesy of Hays et al." Ivantis lacks knowledge or information sufficient to form a belief about the truth of Plaintiff's remaining allegations and therefore denies them.

56. Ivantis lacks knowledge or information sufficient to form a belief about the truth of Plaintiff's allegations and therefore denies them.

57. Ivantis admits that the Samet article states that "[t]he study demonstrated minimal disruption to SC and CC anatomy and patency, with the 8 mm design having a lower potential for CC obstruction due to reduced contact with SC outer wall." Ivantis denies any and all remaining allegations in paragraph 57.

58. Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that the Hydrus® Microstent "is designed to have adequate structural thickness to support the tissue of the canal while providing maximum open flow areas through the canal." Ivantis denies any and all remaining allegations in paragraph 58.

59. Ivantis lacks knowledge or information sufficient to form a belief about the truth of Plaintiff's allegations and therefore denies them.

60. Ivantis lacks knowledge or information sufficient to form a belief about the truth of Plaintiff's allegations and therefore denies them.

61. Ivantis denies that the Hydrus® Microstent meets the claim limitation reciting "support contacts less than 30% of C" in certain claims of the '482, '443, and '742 patents. Ivantis lacks knowledge or information sufficient to form a belief about the truth of Plaintiff's remaining allegations and therefore denies them.

62. Ivantis admits that the FDA's premarket approval application ("PMA") letter to Ivantis, Inc. states that the "Hydrus Microstent is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG)." Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state that "[t]he microstent implantation procedure should be performed after completion of cataract extraction and intraocular lens implantation." Ivantis admits that the Hydrus® Microstent Instructions for Use (C00256 Rev A.1) state to "[c]reate a corneal incision at one of the recommended incision locations as follows (refer to Figure 4). . . 5. Inject ophthalmic viscoelastic into the anterior chamber, unless enough viscoelastic remains from cataract procedure. A high molecular weight cohesive viscoelastic is recommended. Verify eye is firm but do not overinflate. The anterior chamber should be maintained at moderate AC pressure (approximately 15 – 20 mmHg) for an optimal view and microstent delivery. 6. Remove the Hydrus Microstent from the packaging, remove the cannula protector and adjust the cannula orientation for proper hand position. 7. Advance the microstent slightly out of the cannula then retract the implant back into the cannula to position the implant just behind the cannula opening. 8. Insert the cannula

through the corneal incision as shown in Figure 4. 9. Replace the gonioprism lens onto the cornea to establish view of the anterior chamber angle and the cannula tip. Target the trabecular meshwork four clock hours counter clockwise from the entry point for right-handed access (opposite for left-handed access). The approach of the delivery cannula to the target tissue area should be lateral and not across the pupil, so that the cannula angle of approach is not steep. (Figure 4) 10. Pierce the trabecular meshwork by aiming the cannula tip at a slight angle anteriorly (approximately 15 degrees) toward the target. After piercing the TM, the cannula tip should slide gently into Schlemm's canal. Care should be taken with cannula tip approach to fully incise the TM and position the cannula against the posterior wall of Schlemm's canal. 11. When the cannula tip is in the canal and the first window of the microstent is visible, align the cannula to be parallel with the iris. Continue to advance the microstent by rolling the wheel slowly. If resistance is felt, stop advancement, retract if necessary and readjust the position of the cannula. 12. Visually confirm the windows of the microstent entering the canal. The windows should be visible during advancement. The microstent should appear 'dull' during advancement and behind the TM. A shiny stent appearance means the microstent is in front of the TM and not in Schlemm's canal. If the microstent cannot be visualized during delivery, the microstent may be posterior to Schlemm's canal. Retract the implant and redeliver the microstent. 13. Continue to advance the microstent until a physical stop is felt and the interlock releases the microstent. Verify that the inlet of the microstent is positioned in the anterior chamber. 14. If repositioning of the microstent is desired, recapture the microstent by engaging the inlet onto the interlock and reversing the wheel. Alternatively, a Kuglen hook or micro-forceps may be used to reposition the microstent. 15. If the interlock does not appear to release the microstent, slightly withdraw the cannula tip from the TM. After this cannula tip adjustment, the microstent should release. Caution: If the microstent does

not release from the interlock, or if the microstent cannot be retracted into the cannula, withdraw the entire delivery system from the eye. 16. After release of the microstent from the delivery system, take care to remove the cannula tip from the eye without contacting the microstent. 17. Completely irrigate and aspirate the viscoelastic from the anterior segment. 18. Close the corneal incision according to normal practice and verify the eye has been re-pressurized." Ivantis denies any and all remaining allegations in paragraph 62.

63. Admitted.

64. Denied.

65. Denied.

66. Denied.

**FIRST CAUSE OF ACTION: INFRINGEMENT OF U.S. PAT. NO. 8,287,482**

67. Ivantis restates its Answers to paragraphs 1 through 66 as if fully set forth herein.

68. Denied.

69. Denied.

70. Ivantis admits that a claim chart is attached to the First Amended Complaint as Exhibit E. Ivantis denies any and all remaining allegations of paragraph 70.

71. Denied.

72. Denied.

**SECOND CAUSE OF ACTION: INFRINGEMENT OF U.S. PAT. NO. 9,370,443**

73. Ivantis restates its Answers to paragraphs 1 through 72 as if fully set forth herein.

74. Denied.

75. Ivantis admits that a claim chart is attached to the First Amended Complaint as Exhibit F. Ivantis denies any and all remaining allegations of paragraph 75.

76. Denied.

77. Denied.

**THIRD CAUSE OF ACTION: INFRINGEMENT OF U.S. PAT. NO. 9,486,361**

78. Ivantis restates its Answers to paragraphs 1 through 77 as if fully set forth herein.

79. Denied.

80. Denied.

81. Denied.

82. Ivantis admits that a claim chart is attached to the First Amended Complaint as Exhibit G. Ivantis denies any and all remaining allegations of paragraph 82.

83. Denied.

84. Denied.

**FOURTH CAUSE OF ACTION: INFRINGEMENT OF U.S. PAT. NO. 10,314,742**

85. Ivantis restates its Answers to paragraphs 1 through 84 as if fully set forth herein.

86. Denied.

87. Denied.

88. Ivantis admits that a claim chart is attached to the First Amended Complaint as Exhibit H. Ivantis denies any and all remaining allegations of paragraph 88.

89. Denied.

90. Denied.

**PRAYER FOR RELIEF**

The First Amended Complaint recites a prayer for relief for which no response is required. To the extent an answer is required, Ivantis denies that Plaintiff is entitled to any remedy or relief.

**DEMAND FOR JURY TRIAL**

Ivantis joins Plaintiff's request for a jury trial for all issues triable by jury.

## GENERAL DENIAL

Ivantis denies all allegations in Plaintiff's First Amended Complaint not expressly admitted.

## DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or the truth of any allegation in the First Amended Complaint, Ivantis relies upon the following defenses, whether pled as an affirmative defense or otherwise.

## FIRST DEFENSE (NON INFRINGEMENT)

Ivantis does not infringe (literally or under the doctrine of equivalents), and at all relevant times to this action has not infringed, any valid and enforceable claim of the Patents-in-Suit.

## SECOND DEFENSE (INVALIDITY)

The Patents-in-Suit are invalid for failure to satisfy one or more of the conditions and requirements of patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, or under any of the judicially created doctrines of invalidity.

## THIRD DEFENSE (FAILURE TO STATE A CLAIM)

The First Amended Complaint fails to state a claim upon which relief can be granted.

## FOURTH DEFENSE (NO WILLFUL INFRINGEMENT)

Ivantis has not willfully infringed, and does not willfully infringe, any valid and enforceable claim of any of the Patents-in-Suit.

## FIFTH DEFENSE (NO EXCEPTIONAL CASE)

Ivantis's actions in defending this case, or otherwise, do not give rise to an exceptional case in Plaintiff's favor under 35 U.S.C. § 285.

**SIXTH DEFENSE (NO INJUNCTIVE RELIEF)**

Plaintiff is not entitled to preliminary and/or permanent equitable relief, including but not limited to a preliminary and/or permanent injunction because they cannot meet any of the multi-factor tests required for demonstrating a right to such injunctive relief and because of Plaintiff's delay in seeking to enforce the Patents-in-Suit.

**SEVENTH DEFENSE (NOTICE AND DAMAGES)**

Plaintiff is not entitled to any damages for the purported infringement of the Patents-in-Suit pursuant to 35 U.S.C. §§ 284 and 287, including, but not limited to, any interest or trebled damages. Plaintiff's claims for a reasonable royalty and/or lost profits are limited to any infringement committed no more than six (6) years prior to the filing of the Complaint, pursuant to 35 U.S.C. § 286. To the extent Plaintiff failed to comply with the notice provisions of 35 U.S.C. § 287, Plaintiff may not recover a reasonable royalty and/or lost profits for alleged infringement committed prior to the filing of its Complaint.

**EIGHTH DEFENSE (PROSECUTION HISTORY ESTOPPEL)**

Plaintiff is estopped from construing any valid and enforceable claim of the Patents-in-Suit to cover or include, either literally or by application of the doctrine of equivalents, devices manufactured, used, imported, sold, offered for sale, or imported by Ivantis, or methods used by Ivantis, because of admissions and statements to the United States Patent and Trademark Office during prosecution of the application leading to the issuance of the Patents-in-Suit.

**ADDITIONAL DEFENSES**

Ivantis reserves the right to assert any additional defenses or counterclaims that discovery may reveal.

## IVANTIS' DECLARATORY JUDGMENT COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Ivantis, Inc. ("Ivantis" or "Counterclaim-Plaintiff") demands a trial by jury on all issues so triable and asserts the following counterclaims against Plaintiff/Counterclaim-Defendant Sight Sciences, Inc. ("Sight Sciences" or "Plaintiff"):

## INTRODUCTION

1. Ivantis is dedicated to the development of innovative solutions for glaucoma therapy. Ivantis spent years and millions of dollars developing the Hydrus® Microstent, an FDA-approved, revolutionary, minimally invasive glaucoma surgery (MIGS) technology implant indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG). The Hydrus® Microstent is a less invasive surgery that allows for fewer complications and faster healing times than traditional glaucoma surgery.

2. Sight Sciences has never been and is not now in the business of selling surgical implants for the treatment of glaucoma. Sight Sciences does not sell any products that practice the Patents-in-Suit. Sight Sciences waited until September 16, 2021, to sue Ivantis, over three years after the Hydrus® Microstent received FDA approval.

3. As this lawsuit will reveal, Ivantis is a true innovator and does not infringe the Patents-in-Suit, which are invalid and should never have issued.

## PARTIES

4. Ivantis, Inc. ("Ivantis") is a corporation organized under the laws of Delaware with its corporate headquarters at 201 Technology Dr., Irvine, CA 92618.

5. Upon information and belief, Sight Sciences, Inc. ("Sight Sciences") is a corporation organized under the laws of Delaware with its corporate headquarters at 4040 Campbell Ave., Suite 100, Menlo Park, CA 94025.

## NATURE OF THE ACTION

6. Ivantis seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that U.S. Patent Nos. 8,287,482 ("the '482 patent"); 9,370,443 ("the '443 patent"); 9,486,361 ("the '361 patent"); and 10,314,742 ("the '742 patent") (collectively, "Patents-in-Suit") are invalid and/or not infringed.

## JURISDICTION AND VENUE

7. This Court has exclusive subject matter jurisdiction over this action pursuant to federal question jurisdiction, 28 U.S.C. §§ 1331, 1338; and the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

8. This Court has personal jurisdiction over Sight Sciences because it has subjected itself to the jurisdiction of this Court by filing the First Amended Complaint.

9. Venue in this Court is proper based on the choice of forum by Sight Sciences and pursuant to 28 U.S.C. §§ 1391(b)-(c), and 1400(b).

## FACTUAL BACKGROUND

10. On or about October 16, 2012, the '482 patent issued to named inventors David Y. Badawi and Paul Badawi.

11. On or about June 21, 2016, the '443 patent issued to named inventors David Y. Badawi and Paul Badawi.

12. On or about November 8, 2016, the '361 patent issued to named inventors David Y. Badawi and Paul Badawi.

13. On or about June 11, 2019, the '742 patent issued to named inventors David Y. Badawi and Paul Badawi.

14. Sight Sciences purports to be the owner of each of the Patents-in-Suit.

15. On September 16, 2021, Sight Sciences filed a lawsuit against Ivantis asserting that Ivantis' Hydrus® Microstent infringes the Patents-in-Suit.

16. Pursuant to 28 U.S.C. § 2201(a), an actual and justiciable controversy has arisen and exists between Ivantis and Sight Sciences. Ivantis is entitled to a judicial determination and declaration that it has not infringed and is not infringing the Patents-in-Suit, and that the Patents-in-Suit are invalid.

## COUNT I

## DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '482 PATENT

17. Ivantis repeats and re-alleges paragraphs 1–16 as if fully set forth herein.

18. Sight Sciences has brought claims against Ivantis alleging infringement of at least one claim of the '482 patent.

19. A real, immediate, and justiciable controversy exists between Sight Sciences and Ivantis regarding Ivantis's alleged infringement of the '482 patent.

20. Ivantis has not infringed and is not infringing any valid and enforceable claim of the '482 patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, the Hydrus® Microstent does not meet each and every limitation of claim 1 of the '482 patent because the Hydrus® Microstent does not meet the limitation where "the support contacts less than 30% of C."

21. Ivantis is entitled to a declaratory judgment that Ivantis does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid and enforceable claim of the '482 patent, either literally or under the doctrine of equivalents.

## COUNT II

## DECLARATORY JUDGMENT OF INVALIDITY OF THE '482 PATENT

22. Ivantis repeats and re-alleges paragraphs 1–21 as if fully set forth herein.

23. Sight Sciences has brought claims against Ivantis alleging infringement of at least one claim of the ’482 patent.

24. Ivantis alleges that the claims of the ’482 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112.

25. A present, genuine, and justiciable controversy exists between Ivantis and Sight Sciences regarding, *inter alia*, the validity of the claims of the ’482 patent.

26. Ivantis is entitled to a declaration that one or more claims, including at least claims 1 and 63, of the ’482 patent are invalid.

## COUNT III

## DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE ’443 PATENT

27. Ivantis repeats and re-alleges paragraphs 1–26 as if fully set forth herein.

28. Sight Sciences has brought claims against Ivantis alleging infringement of at least one claim of the ’443 patent.

29. A real, immediate, and justiciable controversy exists between Sight Sciences and Ivantis regarding Ivantis’s alleged infringement of the ’443 patent.

30. Ivantis has not infringed and is not infringing any valid and enforceable claim of the ’443 patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, the Hydrus® Microstent does not meet each and every limitation of claim 1 of the ’443 patent because the Hydrus® Microstent does not meet the limitation where “the support contacts less than 30% of C.”

31. Ivantis is entitled to a declaratory judgment that Ivantis does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid and enforceable claim of the ’443 patent, either literally or under the doctrine of equivalents.

## COUNT IV

## DECLARATORY JUDGMENT OF INVALIDITY OF THE ’443 PATENT

32. Ivantis repeats and re-alleges paragraphs 1–31 as if fully set forth herein.

33. Sight Sciences has brought claims against Ivantis alleging infringement of at least one claim of the ’443 patent.

34. Ivantis alleges that the claims of the ’443 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112.

35. A present, genuine, and justiciable controversy exists between Ivantis and Sight Sciences regarding, inter alia, the validity of the claims of the ’443 patent.

36. Ivantis is entitled to a declaration that one or more claims, including at least claim 1, of the ’443 patent are invalid.

## COUNT V

## DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE ’361 PATENT

37. Ivantis repeats and re-alleges paragraphs 1–36 as if fully set forth herein.

38. Sight Sciences has brought claims against Ivantis alleging infringement of at least one claim of the ’361 patent.

39. A real, immediate, and justiciable controversy exists between Sight Sciences and Ivantis regarding Ivantis’s alleged infringement of the ’361 patent.

40. Ivantis has not infringed and is not infringing any valid and enforceable claim of the ’361 patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, the Hydrus® Microstent does not meet each and every limitation of claim 1 of the ’361 patent because the Hydrus® Microstent does not comprise “an arcuate member, wherein at least a portion of the arcuate member has a radius of curvature smaller than a radius of curvature of Schlemm’s canal.”

41. Ivantis is entitled to a declaratory judgment that Ivantis does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid and enforceable claim of the ’361 patent, either literally or under the doctrine of equivalents.

## COUNT VI

## DECLARATORY JUDGMENT OF INVALIDITY OF THE ’361 PATENT

42. Ivantis repeats and re-alleges paragraphs 1–41 as if fully set forth herein.

43. Sight Sciences has brought claims against Ivantis alleging infringement of at least one claim of the ’361 patent.

44. Ivantis alleges that the claims of the ’361 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112.

45. A present, genuine, and justiciable controversy exists between Ivantis and Sight Sciences regarding, inter alia, the validity of the claims of the ’361 patent.

46. Ivantis is entitled to a declaration that one or more claims, including at least claim 1, of the ’361 patent are invalid.

## COUNT VII

## DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '742 PATENT

47. Ivantis repeats and re-alleges paragraphs 1–46 as if fully set forth herein.

48. Sight Sciences has brought claims against Ivantis alleging infringement of at least one claim of the '742 patent.

49. A real, immediate, and justiciable controversy exists between Sight Sciences and Ivantis regarding Ivantis's alleged infringement of the '742 patent.

50. Ivantis has not infringed and is not infringing any valid and enforceable claim of the '742 patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, the Hydrus® Microstent does not meet each and every limitation of claim 1 of the '742 patent because the Hydrus® Microstent does not comprise "an arcuate member, wherein at least a portion of the arcuate member has a radius of curvature smaller than a radius of curvature of Schlemm's canal."

51. Ivantis is entitled to a declaratory judgment that Ivantis does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid and enforceable claim of the '742 patent, either literally or under the doctrine of equivalents.

## COUNT VIII

## DECLARATORY JUDGMENT OF INVALIDITY OF THE '742 PATENT

52. Ivantis repeats and re-alleges paragraphs 1–51 as if fully set forth herein.

53. Sight Sciences has brought claims against Ivantis alleging infringement of at least one claim of the '742 patent.

54. Ivantis alleges that the claims of the '742 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112.

55. A present, genuine, and justiciable controversy exists between Ivantis and Sight Sciences regarding, inter alia, the validity of the claims of the '742 patent.

56. Ivantis is entitled to a declaration that one or more claims, including at least claim 1, of the '742 patent are invalid.

## ATTORNEYS' FEES

This is an exceptional case entitling Ivantis to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

## DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Ivantis hereby respectfully requests a jury trial on all issues and claims so triable.

## PRAYER FOR RELIEF

WHEREFORE, Ivantis requests the following judgments and seeks the following relief:

(i) That all claims against Ivantis be dismissed with prejudice and that all relief requested by Sight Sciences be denied;

(ii) That a judgment be entered declaring that Ivantis has not infringed and does not infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;

(iii) That a judgment be entered declaring that the claims of the Patents-in-Suit are invalid and/or unenforceable for failure to comply with the statutory provisions of

Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112;

(iv) An award of Ivantis' costs as the prevailing party;

(v) That a judgment be entered declaring that this case is exceptional under 35 U.S.C. § 285, and accordingly that Ivantis is entitled to recover reasonable attorneys' fees and costs upon prevailing in this action; and

(vi) That Ivantis be awarded such other relief that the Court deems just and proper.

Dated: January 24, 2022

**FISH & RICHARDSON P.C.**

*/s/ Warren K. Mabey Jr.*

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